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Attitudes Toward Risk and Informed Consent for Research on Medical Practices:

A Cross-sectional Survey

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Abstract

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Background—The U.S. Office for Human Research Protections has proposed that end points of randomized trials comparing the effectiveness of standard medical practices are risks of research that would require disclosure and written informed consent, but data are lacking on the views of potential participants.

Objective—To assess attitudes of U.S. adults about risks and preferences for notification and consent for research on medical practices.

Design—Cross-sectional survey conducted in August 2014.

Setting—Web-based questionnaire.

Patients—1095 U.S. adults sampled from an online panel (*n* = 805) and an online convenience river sample (*n* = 290).

Measurements—Attitudes toward risk, informed consent, and willingness to participate in 3 research scenarios involving medical record review and randomization of usual medical practices.

Results—97% of respondents agreed that health systems should evaluate standard treatments. Most wanted to be asked for permission to participate in each of 3 scenarios (range, 75.2% to 80.4%), even if it involved only medical record review, but most would accept nonwritten (oral) permission or general notification if obtaining written permission would make the research too difficult to conduct (range, 70.2% to 82.7%). Most perceived additional risk from each scenario (range, 64.0% to 81.6%).

Limitation—Use of hypothetical scenarios and a nonprobability sample that was not fully representative of the U.S. population.

Conclusion—Most respondents preferred to be asked for permission to participate in observational and randomized research evaluating usual medical practices, but they are willing to accept less elaborate approaches than written consent if research would otherwise be impracticable. These attitudes are not aligned with proposed regulatory guidance.

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The emergence of studies conducted in health care settings that blur the distinction between research and clinical practice has fanned a debate (1–5) that began in March 2013 when the U.S. Office for Human Research Protections (OHRP) criticized a study (6) comparing target oxygen saturation levels in premature infants (7). The debate revolves around which risks should be attributed to research that compares 2 or more commonly used clinical practices by randomly assigning participants between them. On 24 October 2014, the OHRP announced draft guidance clarifying that, for studies that compare treatments and randomly assign patients, the risks of the treatments should be considered risks of research and disclosed as such (8). But many large ongoing studies of this type, such as those conducted by the National Institutes of Health Collaboratory (9), have not required such disclosures; indeed documented informed consent for such studies may be prohibitively difficult or logistically impossible. According to OHRP, however, in observational studies that compare 2 treatments chosen by clinicians and their patients, the risks of treatment are not considered

to be risks of research and thus are not currently required to be disclosed in the informed consent process (6, 10).

Research on medical practices (ROMP) poses challenges for the protection of human subjects and informed consent. For such research, which is typically conducted in the context of patients receiving care from their physicians, the assessment of risk and approach to informed consent can differ from research that tests new interventions or that is conducted by researchers not providing care to the patient participants (11–14). Current regulations in the United States instruct institutional review boards (IRBs) to "consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research)" (10). Further, the current regulatory framework uses risk categorization to drive specific approaches to informed consent (15, 16). For example, the ability to alter or waive informed consent is only possible for research that "involves no more than minimal risk to the subjects" (17). But the draft guidance defines the risks associated with the standard treatments being evaluated as risks of research if "a standard of care that at least some of the individual subjects will be assigned to receive will be different from the standard of care that they would have received if they were not participating in the study;" further, the guidance requires that these risks must be disclosed to participants (8). The draft guidance is intended to assist institutional review boards in interpreting federal regulations. It may, however, run counter to the ethical principle of respect for persons underlying the regulations to the extent that it takes a narrow view of participant preferences, values, and concerns about research, especially with how participants weigh and balance benefits of research relative to perceived risks (15).

Framing the guidance more appropriately is difficult given the absence of data about the views of potential participants. Empirical data can contribute to normative and policy deliberations by examination of how the public considers the risks of randomization and how the public makes tradeoffs between preferences for notification or permission to participate and the ability of researchers to conduct ROMP. We therefore conducted a survey among a sample of U.S. adults to assess these issues in the context of hypothetical research scenarios involving observational or randomized studies of standard medical practices.

Methods

Overview

We conducted a Web-based survey to assess attitudes about ROMP in August 2014. To explain key features of ROMP, we developed 3 narrative videos that were embedded in the survey. We developed the survey questionnaire and pilot-tested the videos using focus groups. This study was approved by the University of Washington and Stanford University Institutional Review Boards.

Sample Selection

Our sample was obtained from Research Now and derived from members of an online research panel and a “river” (convenience) sample of Internet users invited to participate when visiting general, social media, and loyalty Web sites. Panel members received a small incentive by a points-based reward program, and their identity was validated by detection of a unique computer ID. Multiple survey completions were avoided by use of a unique URL for each survey. Quota sampling was used to ensure inclusion of key population subgroups by geography (Northeast, Midwest, South, and West), gender, age, race, and ethnicity.

Development of Narrative Videos

Because this type of research is not familiar to most people, we created 3 animated narrative videos (with Alex Thomas, MD, and health communication specialist Gary Ashwal, both of Booster Shot Media), each 2 to 3 minutes long, that focused on the variability in use of approved antihypertension medications and research to learn which treatments are better. With Booster Shot Media, the research team identified key concepts about ROMP that distinguish it from other clinical research and were addressed in the survey. On the basis of these concepts, Booster Shot Media developed storyboards, scripts, and draft videos, each of which was revised in collaboration with the research team. We showed the videos as part of the focus groups and solicited feedback to inform revisions for clarity (for example, we slowed the narration in response to comments that it was too fast) and overcome common misconceptions (for example, that medical research only compares treatments with placebo, rather than with each other). The first video explains factors that influence variation in clinical practice, the second explains randomization and medical record review, and the third explains 3 approaches to notifying patients about research and obtaining their permission to participate. We used conventional terms for notification (“general information”), oral permission (“verbal permission”), and written consent (“written agreement”). We described the spectrum of medical record review and randomization comparing usual treatments as “research on medical practices” because such terms as “learning health systems,” “comparative effectiveness research,” and “pragmatic trials” are not commonly used by the public. We believed that “research on medical practices” was more descriptive, which was confirmed in our focus groups.

Survey Development and Administration

To develop the survey, we conducted 8 focus groups of 4 to 7 participants each and 2 small-group interviews of 2 to 3 participants each; participants were recruited from clinics at 3 health care institutions. We revised the survey on the basis of review by expert consultants and through 13 cognitive interviews of participants derived from the focus group sampling frame and patrons of a public library by using the “think aloud” technique (18).

The survey began with questions about attitudes toward research, physicians, and health systems, interspersed with the 3 videos and questions to assess understanding of ROMP concepts. The second section asked questions about preferences for notification and permission to enroll in ROMP, perceptions of risk, and willingness to participate in ROMP in the context of 3 scenarios. The first scenario described a medical record review comparing the outcomes of 3 medications in patients newly diagnosed with hypertension,

with the medications being described as approved by the U.S. Food and Drug Administration and prescribed on the basis of physician judgment and patient preferences. The second scenario described a variant of the first scenario in which patients were randomly assigned to one of these medications, in an unblinded manner, with usual clinical follow-up. The scenario stated that "the doctor will not change the [assigned] medication unless the doctor or patient has concerns." The third scenario described a similar randomized study comparing 3 medications for "a more serious condition that increases your risk for stroke." The last section of the survey consisted of questions about demographic characteristics and prior experience with health care for serious illness and clinical research. The videos (19–21) and the survey instrument (22) are available at the ROMP Ethics Study Web site (https://rompethics.iths.org/). Readers are invited to take the online survey (http://trn.co1.qualtrics.com/SE/?SID=SV_3vISKwFfRV1LV53) from 14 April 2015 to 18 August 2015. Selected survey questions and descriptive data on responses are provided in Appendix Table 1 (available at www.annals.org). Participants from the research panel and river sample were invited to take the survey and were sent a single e-mail that contained a link to the survey Web site.

Statistical Analysis

Sample characteristics are shown in Table 1 alongside data from the U.S. Census Bureau (23) and the Centers for Disease Control and Prevention National Health Interview Survey (24). The survey required a response to all items, with the exception that respondents were given the option of "prefer not to answer" for the questions about household income and education. Estimates of sampling error could not be calculated because both samples are made up of volunteers only; therefore, the probabilities of selection and thus response rates cannot be calculated because the sampling frame is unknown (25).

Role of the Funding Source

The study was funded by the National Center for Advancing Translational Sciences at the National Institutes of Health. The funding source did not participate in the design, conduct, or analysis of the study or in the decision to submit the manuscript for publication.

Results

Respondent Characteristics

Demographic characteristics of survey respondents are shown in Table 1 and Appendix Table 2 (available at www.annals.org). Of the 1095 completed survey responses we received, 805 were from the panel and 290 were from the river sample. Results are reported for the combined group of respondents from the panel and river samples, with no weighting or adjustments applied. We report the response metrics currently recommended for online surveys (25, 26). The completion rate representing all respondents who attempted to complete a survey even if they were screened out was 41.6% (1335 of 3208 respondents) for the panel survey and 90.1% (472 of 524 respondents) for the river survey. The study-specific eligibility rate is equivalent to Response Rate 6 as defined by the American Association for Public Opinion Research for a study-specific sample (27). The eligibility rate was 60.3% (805 completed surveys/[805 completed + 530 screened out]) in the panel

survey and 61.2% (289 completed surveys/[289 completed + 183 screened out]) in the river survey.

Demographic characteristics (geography, gender, age, race, and ethnicity) of respondents differed from those reported in the 2013 U.S. Census data (23) in that our sample had a lower proportion of Asian Americans, fewer respondents in the 21- to 26-year age group years but more in the 27- to 44-year age group, and respondents with higher average educational level and household income (23). Self-reported health status was somewhat poorer in our sample relative to the national average, with smaller percentages of our sample reporting excellent or very good health (24); 95.4% and 85.0% of respondents trusted their physicians and health systems, respectively, to put their well-being above all other considerations (Appendix Table 1). Respondents correctly answered a mean of 5.04 of the 6 questions about understanding of ROMP (84%) (Appendix Table 1). The percentage of respondents answering all 6 questions correctly ranged from 76.5% to 95.3%.

Support for ROMP

Respondents showed strong support for research to determine which standard treatments are best; 97% agreed (74.3% strongly) that health systems should conduct this type of research (Table 2), and 92.8% indicated that it was always (15.3%), usually (46.4%), or sometimes (31.1%) acceptable for health systems to use randomization to compare how well standard treatments work. However, 75.4% had not participated in a randomized clinical study (Appendix Table 1).

Preferences for Notification or Permission to Participate in ROMP

Most respondents preferred to have a discussion with their provider followed by either written or oral permission to participate in each of the 3 ROMP scenarios (Table 3). The proportions of respondents who indicated a preference for written permission for each of the 3 scenarios were similar: 51.0% for the medical record review scenario, 47.2% for the hypertension scenario, and 52.4% for the more serious condition scenario. The proportions of respondents who indicated a preference for written permission for the randomized scenario of the more serious condition (52.4%) and the medical record review (51.0%) or randomized hypertension (47.2%) scenarios were very similar.

To assess these preferences relative to the ability to conduct research among respondents who initially indicated a preference for either discussion plus oral or written permission, we further measured their preferences if getting permission in one form or the other “would make this research too difficult to carry out.” One of the response options provided was, “I would prefer that the research not be conducted” (Table 4). For all 3 scenarios, most preferred a less demanding approach rather than the research not being conducted. Most respondents who preferred written or oral permission for each of the 3 scenarios still supported doing research if permission was too difficult to obtain, although more indicated a preference that research not be conducted for the randomized study of the more serious condition (37.2%) or hypertension (31.8%) than research using medical records (26.8%) (Table 5).

Of participants surveyed, 84.5% preferred that they be asked permission to participate in the medical records review study by their physician as opposed to by a researcher or research nurse not involved in their care, whereas 85.2% preferred their physician in the hypertension scenario and 86.8% in the more serious condition scenario (see survey questions 12, 21, and 35 in Appendix Table 1).

Perceptions of Risk and Willingness to Participate in ROMP

In general, most respondents perceived "a little" more risk with each scenario than with "just having their doctor prescribe the medications" (Table 6). A higher percentage perceived the risks of ROMP to be "a lot" more with randomization for hypertension or a serious condition than for medical record review, and a higher percentage perceived no additional risk from research using medical record review than from randomized studies. In addition, whereas most respondents were willing to participate in all 3 scenarios, more indicated a willingness to participate in the medical record review scenario than the randomized studies for hypertension or a more serious condition (Table 6).

Discussion

Almost all respondents to our survey supported ROMP, including the use of randomization, and were willing to participate in such research. Most, however, wanted to be asked for their permission to participate. Of note, the percentage preferring written permission for research using medical records was almost as high as that for scenarios involving randomization. This suggests that persons want to be asked for permission to participate in such research regardless of whether it affects treatment decisions. These findings are consistent with other studies that reveal broad support for, and willingness to participate in, research (27) but also a strong desire to be asked for permission before research using medical records (28), biospecimens (29, 30), or cluster randomization (31). These data also suggest that, unlike the OHRP's interpretation of the federal regulations, the public does not base disclosure preferences about research solely on whether the research plan determines treatment assignment. In addition, the expressed preference for permission to be obtained by physicians rather than researchers not involved in care seems contrary to the regulatory requirement that "investigators" obtain informed consent (32).

Given the widespread preference among our sample for being asked permission to participate in both randomized and nonrandomized ROMP, we were surprised to find that, when asked to choose between less demanding approaches to consent or precluding research from being done, most respondents were willing to accept less demanding approaches. Fewer even preferred notification through the receipt of general information, without express permission, over not allowing the research to proceed. This suggests that preferences are contextual or contingent upon certain conditions being met; although persons value both research and the ability to agree to or decline participation in studies, such as those described in our scenarios, many prioritize the former over the latter. Thus, in cases in which conducting research with particular informed consent requirements may be impractical, such as written documentation, most respondents preferred that the research go forward.

The finding that most respondents thought there was at least a little more risk from research than usual clinical care, even when the research involves only medical record review, suggests that persons do perceive research-specific risks in ROMP. Of note, there was only a small difference between the proportion of respondents who felt that medical record review posed “a little more risk” than usual care and the proportion who felt that way about the randomization scenarios. This suggests that a substantial portion of respondents do not regard the possibility of being randomly assigned to a treatment different from what they would otherwise have received as the source of the perceived risk. Again, this perception of risk from research involving only the review of medical records contrasts with the OHRP guidance, which does not consider the risks associated with standard care in an observational study to be risks of research (6). But we do not know the nature of the risks that respondents might have envisioned as they considered the 3 scenarios.

Our study has some limitations. First, our survey asked about hypothetical scenarios, so notification and permission preferences and willingness to participate in actual situations may differ. Second, we cannot assess the effects of nonresponse bias due to our sampling method. We chose our sampling method to obtain an overall sample with diversity in geography, age, gender, race, and ethnicity. But our sample differed somewhat from the general U.S. population in terms of race, age, income, education, and self-reported health status. Although we do not know how our sample compares with potential participants in ROMP, at least 1 population-based study found that poor health and some college-level or higher education were predictors of participation in clinical trials in general (33), suggesting that our sample may be similar to persons likely to participate in ROMP.

Our findings suggest strong support for research that compares usual clinical practices to determine the best ways of treating a particular condition and willingness to participate in such research. Respondents also favored being asked for permission to participate in this research, regardless of whether it affects treatment decisions; thus our results indicate that respondents might not attribute and categorize risks in the same way as the federal regulatory draft guidance. These findings may indicate, on one hand, that federal regulations do not go far enough to ensure that research participants are informed about and asked for permission to participate in observational research, including studies of de-identified data that are currently not considered human subjects research. If requiring written permission would preclude the conduct of research, however, most persons would rather accept less elaborate notification or approaches to consent than see the research not be done; they thus seem willing to make tradeoffs between imposing full consent requirements and allowing research to proceed.

If the proposed OHRP guidance is adopted, it would define potential differences in outcome as risks of research, and therefore randomized comparative effectiveness research will nearly always need to be classified as greater-than-minimal risk. Thus, the OHRP proposal seems to rule out options that many potential research participants would want to have available, such as a waiver of documentation or a waiver or alteration of consent. Although the OHRP approach could address the concerns of a consent-requiring minority, it may do so at the expense of a research-supporting majority. Fulfilling the ethical principle of respect for persons in the conduct of ROMP requires finding the appropriate balance between the

concerns of participants (which may be broader than current regulatory definitions of risk) and an appreciation of the public's desire for research to be conducted.

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EDITORS' NOTES

Context

Should research that compares standard medical practices require informed consent from participants?

Contribution

This survey of 1095 adults examines attitudes about research that evaluates standard practices. Most respondents were willing to participate in such research but preferred that they be asked for permission, even if the research involved only medical record review. Most (70% to 83%) supported oral permission or general notification if written permission made research impracticable.

Caution

Respondents were not representative of the U.S. population.

Implication

Adults prefer giving informed consent to participate in research about standard practices, but they may agree to simple approaches to consent rather than precluding such research.

Table 1

Characteristics of Respondents*

Characteristic	Respondents (*n* = 1095), %	U.S. Population, %†
Men	49.0	49.4
Age		
21–26 y	7.9	11.0
27–44 y	37.4	32.2
45–64 y	37.2	36.9
≥65 y	17.6	19.8
Race		
White	74.0	73.9
Asian	2.8	5.0
African American	13.1	12.6
Other/multiracial	10.1	8.6
Hispanic ethnicity	16.1	16.9
U.S. census geographic region		
Northeast	18.1	17.7
Midwest	22.1	21.3
South	36.7	37.4
West	23.1	23.5
Education level		
High school or less	13.8	33.8
Some college/associate's degree	30.3	33.1
College graduate	34.2	21.4
Graduate/professional school	21.1	11.7
Prefer not to answer	0.6	NA
Household income		
≤$30 000	15.2	20.8
>$30 000–$55 000	21.3	22.3
>$55 000–$95 000	27.2	26.0
>$95 000	28.3	30.8

Characteristic	Respondents (n = 1095), %	U.S. Population, %†
Prefer not to answer	8.1	NA
Self-reported health status		
Excellent	18.3	35.5
Very good	40.7	30.2
Good	29.0	24.0
Fair	10.8	7.9
Poor	1.3	2.4

NA = not applicable.

*Percentages may not sum to 100 due to rounding.

†Data obtained from the U.S. Census Bureau 2013 Current Population Survey and the Centers for Disease Control and Prevention 2012 National Health Interview Survey.

Table 2

Support for Research on Medical Practices

Response	Respondents (*n* = 1095), *n (%)*
"To find out which standard medical treatments are best, health systems should conduct research."	
Strongly disagree	10 (0.9)
Somewhat disagree	24 (2.2)
Somewhat agree	247 (22.6)
Strongly agree	814 (74.3)
"In your opinion, how acceptable is it for health systems to use randomization to compare how well different standard treatments work?"	
Never acceptable	29 (2.6)
Rarely acceptable	50 (4.6)
Sometimes acceptable	340 (31.1)
Usually acceptable	508 (46.4)
Always acceptable	168 (15.3)

Table 3

Notification and Permission Preferences for Research on Medical Practices

Response	Research Scenario (*n* = 1095), *n (%)*		
	Medical Record Review	**Randomization (Hypertension)**	**Randomization (Serious Condition)**
"If you were newly diagnosed with high blood pressure and this research were happening in your health system, how would you prefer to be notified about this research?"			
No notification	109 (10.0)	71 (6.5)	61 (5.6)
General information	162 (14.8)	212 (19.4)	153 (14.0)
Discussion plus verbal permission	266 (24.2)	295 (26.9)	307 (28.0)
Discussion plus written permission	558 (51.0)	517 (47.2)	574 (52.4)

Table 4

Preferences if Obtaining Permission Would Make Research Too Difficult*

Response	Research Scenario		
	Medical Record Review	Randomization (Hypertension)	Randomization (Serious Condition)
Of those initially preferring "Discussion plus written permission": "If getting written permission or consent would make this research too difficult to carry out, how would you prefer to be notified about this research?"			
Respondents, *n*	558	517	574
No notification, *n (%)*	15 (2.7)	5 (1.0)	11 (1.9)
General information, *n (%)*	84 (15.1)	64 (12.4)	48 (8.4)
Discussion plus verbal permission, *n (%)*	362 (64.9)	322 (62.3)	344 (59.9)
Prefer research not be conducted, *n (%)*	97 (17.4)	126 (24.4)	171 (29.8)
Of those preferring "Discussion plus verbal permission" (after initially preferring written permission): "If getting verbal permission would make this research too difficult to carry out, how would you prefer to be notified about this research?"			
Respondents, *n*	362	322	344
No notification, *n (%)*	14 (3.8)	12 (3.7)	5 (1.5)
General information, *n (%)*	250 (69.1)	209 (64.9)	226 (65.7)
Prefer research not be conducted, *n (%)*	98 (27.1)	101 (31.4)	113 (32.9)
Of those initially preferring "Discussion plus verbal permission": "If getting verbal permission would make this research too difficult to carry out, how would you prefer to be notified about this research?"			
Respondents, *n*	266	295	307
No notification, *n (%)*	27 (10.2)	22 (7.5)	20 (6.5)
General information, *n (%)*	213 (80.1)	242 (82.0)	243 (79.2)
Prefer research not be conducted, *n (%)*	26 (9.8)	31 (10.5)	44 (14.3)

* Percentages may not sum to 100 due to rounding.

Table 5

Total Respondents Who Prefer That the Research Not Be Conducted

Response	Research Scenario, *n (%)*		
	Medical Record Review (*n* = 824)	**Randomization (Hypertension) (*n* = 812)**	**Randomization (Serious Condition) (*n* = 881)**
Initially prefer written or verbal permission, then prefer that research not be conducted	221 (26.8)	258 (31.8)	328 (37.2)

Table 6

Perceptions of Risk and Willingness to Participate in Research on Medical Practices*

Response	Research Scenario (*n* = 1095), *n (%)*		
	Medical Record Review	**Randomization (Hypertension)**	**Randomization (Serious Condition)**
"Compared to just having your doctor prescribe the medications, how much additional risk do you think that there is to you from this research using. . . ."			
None	394 (36.0)	235 (22.5)	202 (18.5)
A little	574 (52.4)	690 (63.0)	624 (57.0)
A lot	127 (11.6)	170 (15.5)	269 (24.6)
"Would you be willing to consider participating in research using. . . ."			
Yes	883 (80.6)	798 (72.9)	738 (67.4)
No	212 (19.4)	297 (27.1)	357 (32.6)

* Percentages may not sum to 100 due to rounding.

Appendix Table 1

Selected Items From the Survey*

Response	Respondents (*n* = 1095), *n (%)*†
Trust	
Q1: How much do you trust the doctor you see most often to put your well-being above all other considerations when treating your medical problems?	
I trust my doctor a lot	629 (57.4)
I trust my doctor somewhat	416 (38.0)
I distrust my doctor somewhat	37 (3.4)
I distrust my doctor a lot	13 (1.2)
Q2: How much do you trust your health system to put your well-being above all other considerations when treating your medical problems? (By health system, we mean the network of doctors and hospitals where you receive care.)	
I trust my health system a lot	330 (30.1)
I trust my health system somewhat	601 (54.9)
I distrust my health system somewhat	119 (10.9)
I distrust my health system a lot	45 (4.1)
Q6: Now we would like you to think about patient trust. To maintain your trust as a patient, how important is it that your doctor tells you when he/she is uncertain about which treatment is best for you?	
Very important to maintain my trust	877 (80.1)
Moderately important to maintain my trust	174 (15.9)
Somewhat important to maintain my trust	35 (3.2)
Not at all important to maintain my trust	9 (0.8)
Q8: When my health system shares information from my medical record with other health systems to improve care for all patients, it notifies me that it is doing so.	
Very important to maintain my trust	698 (63.7)
Moderately important to maintain my trust	250 (22.8)
Somewhat important to maintain my trust	82 (7.5)
Not at all important to maintain my trust	65 (5.9)
Q9: My health system uses an ethics committee to oversee research activities.	
Very important to maintain my trust	760 (69.4)
Moderately important to maintain my trust	258 (23.6)
Somewhat important to maintain my trust	59 (5.4)
Not at all important to maintain my trust	18 (1.6)

Response	Respondents (n = 1095), n (%)[†]
Q10: My health system includes a patient advisory board to help oversee research activities.	
Very important to maintain my trust	655 (59.8)
Moderately important to maintain my trust	331 (30.2)
Somewhat important to maintain my trust	83 (7.6)
Not at all important to maintain my trust	26 (2.4)
Understanding of research on medical practices	
Q3a: Doctors agree about which treatment for high blood pressure is best.	
True	257 (23.5)
(coded as correct response) False	838 (76.5)
Q3b: A doctor's decision about what medication to prescribe is based on multiple influences.	
(coded as correct response) True	1044 (95.3)
False	51 (4.7)
Q3c: Sometimes there is not enough information for doctors to know which standard medical practices are best.	
(coded as correct response) True	934 (85.3)
False	161 (14.7)
Q7a: Trying to figure out the best treatment using medical record review can sometimes give researchers the wrong answer.	
(coded as correct response) True	901 (82.3)
False	194 (17.7)
Q7b: With randomization, you can never change the medication you are taking.	
True	193 (17.6)
(coded as correct response) False	902 (82.4)
Q7c: Randomization is the "gold standard" for comparing medications.	
(coded as correct response) True	899 (82.1)
False	196 (17.9)
Attitudes toward and experiences with research	
Q4: To find out which standard medical treatments are best, health systems should conduct research.	
Strongly agree	814 (74.3)
Somewhat agree	247 (22.6)
Somewhat disagree	24 (2.2)
Strongly disagree	10 (0.9)
Q5: Although research on standard medical practices might determine the "best" medical treatment to start with for the average patient, that treatment might not be the best one to start with for me.	

Response	Respondents (n = 1095), n (%)[†]
Strongly agree	655 (59.8)
Somewhat agree	401 (36.6)
Somewhat disagree	35 (3.2)
Strongly disagree	4 (0.4)
Q19: In your opinion, how acceptable is it for health systems to use randomization to compare how well different standard treatments work?	
Always acceptable	168 (15.3)
Usually acceptable	508 (46.4)
Sometimes acceptable	340 (31.1)
Rarely acceptable	50 (4.6)
Never acceptable	29 (2.6)
Q49: Have you ever participated in a randomized clinical study?	
Yes	101 (9.2)
No	826 (75.4)
I don't know	168 (15.3)
Q50: Have any close family members ever participated in a randomized clinical study?	
Yes	84 (7.7)
No	700 (63.9)
I don't know	311 (28.4)
Medical records review scenario	
Q11: If you were newly diagnosed with high blood pressure and this research using medical record review were happening in your health system, how would you prefer to be notified about this research?	
I would not need to be notified about this research using medical record review (skip to Q15)	109 (10.0)
My health system would give me a document containing general information about this research (skip to Q15)	162 (14.8)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q12, then skip to Q14)	266 (24.3)
Doctors or other medical personnel would discuss this research using medical record review with me and then ask for written permission or consent to participate (continue to Q12)	558 (51.0)
Q12: Who would you prefer to ask you for your permission or consent to participate in this research using medical record review? (Total = 824)	
My doctor	696 (84.5)
A researcher or research nurse who is not involved in my care	38 (4.6)
No preference	90 (10.9)

Response	Respondents (n = 1095), n (%)[†]
Q13: If getting written permission or consent would make this research using medical record review too difficult to carry out, how would you prefer to be notified about this research? (Total = 558)	
I would not need to be notified about this research using medical record review (skip to Q15)	15 (2.7)
My health system would give me a document containing general information about this research (skip to Q15)	84 (15.1)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q14)	362 (64.9)
I would prefer this research using medical record review not be conducted (skip to Q15)	97 (17.4)
Q14: If getting verbal permission or consent would make this research using medical record review too difficult to carry out, how would you prefer to be notified about this research? (Total = 628)	
I would not need to be notified about this research using medical record review	41 (6.5)
My health system would give me a document containing general information about this research	463 (73.7)
I would prefer this research using medical record review not be conducted	124 (19.8)
Q15: How would knowing that this research using medical record review was going on in your health system affect your trust in your health system?	
Greatly increase trust in my health system	314 (28.7)
Somewhat increase trust	378 (34.5)
Would not change trust	325 (29.7)
Would not change trust	53 (4.8)
Greatly decrease trust in my health system	25 (2.3)
Q16: How would knowing that this research using medical record review was going on in your health system affect your trust in your doctor?	
Greatly increase trust in my doctor	309 (28.2)
Somewhat increase trust	342 (31.2)
Would not change trust	375 (34.3)
Somewhat decrease trust	52 (4.8)
Greatly decrease trust in my doctor	17 (1.6)
Q17: Would you be willing to consider having your medical records reviewed for this research on high blood pressure medications?	
Yes	883 (80.6)
No	212 (19.4)
Q18: Compared to just having your doctor prescribe the medications, how much additional risk do you think there is to you from this research using medical record review?	
A lot of additional risk	127 (11.6)
A little additional risk	574 (52.4)

Response	Respondents (n = 1095), n (%)[†]
No additional risk	394 (36.0)
Randomization scenario: hypertension	
Q20: If you were newly diagnosed with high blood pressure and this research using randomization were happening in your health system, how would you prefer to be notified about this research?	
I would not need to be notified about this research using randomization (skip to Q24)	71 (6.5)
My health system would give me a document containing general information about this research (skip to Q24)	212 (19.4)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q21, then skip to Q23)	295 (26.9)
Doctors or other medical personnel would discuss this research using medical record review with me and then ask for written permission or consent to participate (continue to Q21)	517 (47.2)
Q21: Who would you prefer to ask you for your permission or consent to participate in this research using randomization? (Total = 812)	
My doctor	692 (85.2)
A researcher or research nurse who is not involved in my care	51 (6.3)
No preference	69 (8.5)
Q22: If getting written permission or consent would make this research using randomization too difficult to carry out, how would you prefer to be notified about this research? (Total = 517)	
I would not need to be notified about this research using randomization (skip to Q24)	5 (1.0)
My health system would give me a document containing general information about this research (skip to Q24)	64 (12.4)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q23)	322 (62.3)
I would prefer this research using randomization not be conducted (skip to Q24)	126 (24.4)
Q23: If getting verbal permission or consent would make this research using randomization too difficult to carry out, how would you prefer to be notified about this research? (Total = 617)	
I would not need to be notified about this research using randomization	34 (5.5)
My health system would give me a document containing general information about this research	451 (73.1)
I would prefer this research using randomization not be conducted	132 (21.4)
Q24: How would knowing that this research using randomization was going on in your health system affect your trust in your health system?	
Greatly increase trust in my health system	221 (20.2)
Somewhat increase trust	312 (28.5)
Would not change trust	439 (40.1)
Somewhat decrease trust	88 (8.0)
Greatly decrease trust in my health system	35 (3.2)

Response	Respondents (n = 1095), n (%)[†]
Q25: How would knowing that this research using randomization was going on in your health system affect your trust in your doctor?	
Greatly increase trust in my doctor	221 (20.2)
Somewhat increase trust	312 (28.5)
Would not change trust	439 (40.1)
Would not change trust	88 (8.0)
Greatly decrease trust in my doctor	35 (3.2)
Q26: Would you be willing to consider participating in this research using randomization?	
Yes	798 (72.9)
No	297 (27.1)
Q29: Compared to just having your doctor prescribe the medications, how much additional risk do you think there is to you from this research using randomization?	
A lot of additional risk	170 (15.5)
A little additional risk	690 (63.0)
No additional risk	235 (21.5)
Q30: To what extent would knowing each of the following affect your willingness to participate in research using randomization, if at all?	
Q30a: Knowing I could change high blood pressure medications if I needed to	
Greatly decrease willingness	77 (7.0)
Somewhat decrease willingness	64 (5.8)
No impact	202 (18.5)
Somewhat increase willingness	298 (27.2)
Greatly increase willingness	454 (41.5)
Q30b: Knowing which high blood pressure medication I was taking	
Greatly decrease willingness	54 (4.9)
Somewhat decrease willingness	71 (6.5)
No impact	320 (29.2)
Somewhat increase willingness	315 (28.8)
Greatly increase willingness	335 (30.6)
Q30c: Knowing my doctor recommended participation	
Greatly decrease willingness	71 (6.5)
Somewhat decrease willingness	54 (4.9)

Response	Respondents (n = 1095), n (%)[†]
No impact	230 (21.0)
Somewhat increase willingness	325 (29.7)
Greatly increase willingness	415 (37.9)
Q30d: Knowing the only way to really know which medication is better would be to use randomization	
Greatly decrease willingness	69 (6.3)
Somewhat decrease willingness	79 (7.2)
No impact	264 (24.1)
Somewhat increase willingness	355 (32.4)
Greatly increase willingness	328 (30.0)
Randomization scenario: more serious condition	
Q34: If you were newly diagnosed with this serious condition and this research using randomization were happening in your health system, how would you prefer to be notified about this research?	
I would not need to be notified about this research using randomization (skip to Q38)	61 (5.6)
My health system would give me a document containing general information about this research (skip to Q38)	153 (14.0)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q35, then skip to Q37)	307 (28.0)
Doctors or other medical personnel would discuss this research using medical record review with me and then ask for written permission or consent to participate (continue to Q35)	574 (52.4)
Q35: Who would you prefer to ask you for your permission or consent to participate in this research using randomization? (Total = 881)	
My doctor	765 (86.8)
A researcher or research nurse who is not involved in my care	53 (6.0)
No preference	63 (7.2)
Q36: If getting written permission or consent would make this research using randomization too difficult to carry out, how would you prefer to be notified about this research? (Total = 574)	
I would not need to be notified about this research using randomization (skip to Q38)	11 (1.9)
My health system would give me a document containing general information about this research (skip to Q38)	48 (8.4)
Doctors or other medical personnel would discuss this research with me and then ask for verbal permission to participate (continue to Q37)	344 (59.9)
I would prefer this research using randomization not be conducted (skip to Q38)	171 (29.8)
Q37: If getting verbal permission or consent would make this research using randomization too difficult to carry out, how would you prefer to be notified about this research? (Total = 651)	
I would not need to be notified about this research using randomization	25 (3.8)
My health system would give me a document containing general information about this research	469 (72.0)

Response	Respondents (n = 1095), n (%)[†]
I would prefer this research using randomization not be conducted	157 (24.1)
Q38: Would you be willing to consider participating in this research using randomization?	
Yes	738 (67.4)
No	357 (32.6)
Q41: Compared to just having your doctor prescribe the medications, how much additional risk do you think there is to you from this research using randomization?	
A lot of additional risk	269 (24.6)
A little additional risk	624 (57.0)
No additional risk	202 (18.5)
Video experience	
Q44: As a result of watching the videos about research comparing medical treatment, how has your willingness to participate in this type of research changed?	
Much more willing to participate	178 (16.3)
A little more willing to participate	379 (34.6)
My willingness to participate has not changed	467 (42.7)
A little less willing to participate	29 (2.7)
Much less willing to participate	42 (3.8)

Q = question.

[*] Percentages may not sum to 100 due to rounding.

[†] Unless otherwise indicated.

Appendix Table 2

Characteristics of Survey Respondents*

Characteristic	Total (*n* = 1095), %	Panel (*n* = 805), %	River Sample (*n* = 290), %
Men	49.0	41.0	71.0
Age			
21–26 y	7.9	4.5	17.2
27–44 y	37.4	30.3	56.9
45–64 y	37.2	43.0	21.0
≥65 y	17.6	22.2	4.8
Race			
White	74.0	72.8	77.2
Asian	2.8	3.9	0.0
African American	13.1	13.3	12.4
Other/multiracial	10.1	10.1	10.3
Hispanic ethnicity	16.1	13.4	23.5
U.S. census geographic region			
Northeast	18.1	18.0	18.3
Midwest	22.1	22.0	22.4
South	36.7	36.7	36.9
West	23.1	23.4	22.4
Education level†			
High school or less	13.8	9.6	25.5
Some college/associate's degree	30.3	29.8	31.7
College graduate	34.2	35.1	31.7
Graduate/professional school	21.1	25.0	10.3
Prefer not to answer	0.6	0.5	0.7
Household income			
≤$30 000	15.2	11.4	25.5
>$30 000–$55 000	21.3	19.1	27.2
>$55 000–$95 000	27.2	26.6	28.6
>$95 000	28.3	33.4	14.4

Characteristic	Total (*n* = 1095), *%*	Panel (*n* = 805), *%*	River Sample (*n* = 290), *%*
Prefer not to answer	8.1	9.4	4.5
Self-reported health status			
Excellent	18.3	17.6	20.0
Very good	40.7	44.0	31.7
Good	29.0	28.2	31.0
Fair	10.8	9.1	15.5
Poor	1.3	1.0	1.7

* Percentages may not sum to 100 due to rounding.

† U.S. education level includes respondents aged ≥18 y; education level for the panel and river sample includes only respondents aged ≥21 y.